

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO**

DISTRICT OF NEW MEXICO

THE REGENTS OF THE UNIVERSITY
OF NEW MEXICO,

Plaintiff,

vs.

GALEN D. KNIGHT, an individual;
and TERENCE J. SCALLEN, an individual;

Defendants.

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Robert J. [Signature]
CLERK AT BUREAU

Cause No.: CIV 99-577 JC/WWD

**THE REGENTS OF THE UNIVERSITY OF NEW MEXICO'S
PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW**

Plaintiff, The Regents of the University of New Mexico ("University"), hereby submits its proposed Findings of Fact and Conclusions of Law for this Court's consideration in connection with the trial concluded on July 3, 2001.¹ These Findings and Conclusions replace, rather than supplement, the pre-trial Findings and Conclusions (*Doc. 285*) submitted by the University.

Findings of Fact

A. Parties

1. The Plaintiff University is a body corporate established under the Constitution and Laws of the State of New Mexico.

¹ An electronic copy is enclosed on disk.

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2. The Defendant Galen D. Knight (“Knight”) is a resident of the State of New Mexico, and the Defendant Terence J. Scallen (“Scallen”) is a resident of the State of California.
3. The allegations of Counts I and III raise issues that arise under the Patent Laws (35 U.S.C. § 1 et seq.). Count III of the Amended Complaint arises under 35 U.S.C. § 256 and 28 U.S.C. § 2201.

B. Jurisdiction and Procedural History

4. This matter was tried on the sole issue of ownership of certain patents and patent applications as alleged in Count I of the Complaint and determination and correction of inventorship of certain specified patents as alleged in Count III. The sole factual issue is whether certain amendments, as hereafter described, made to certain of the patents and patent applications of Count I, as hereafter described, constitute “new matter” in contravention of 35 U.S.C. § 132, last sentence.
5. The Court had earlier entered summary judgment in favor of Plaintiff on Count II of the Complaint, holding that the University is the owner of all right, title, and interest in and to the Beta-Alethine Patents and Applications (as defined in the Amended Complaint). The Court also entered summary judgment on Count IV, holding that Knight and Scallen breached their contractual obligations with the University by failing to execute assignments to the Vitaletheine Patents and Applications and Beta-Alethine Patents and Applications (as such terms are defined in the Amended Complaint). The Court also entered summary judgment

that the Defendants are the only joint inventors of one of the Vitaletheine Issued Patents, U.S. Patent No. 5,370,868 (Count III).

6. Counts VI through VII of the Complaint were dismissed on the motion of Plaintiff University.

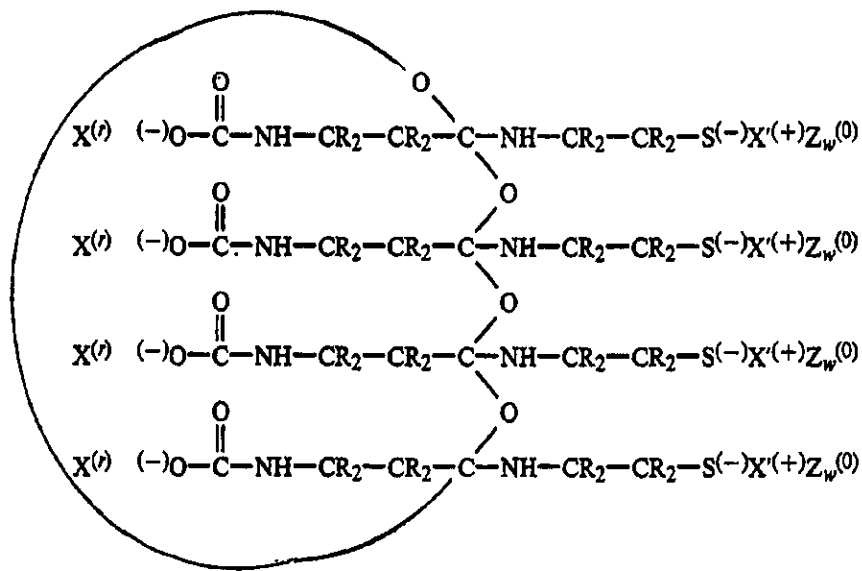
C. Patents and Patent Applications At Issue

7. The patent application (Serial No. 08/317,548) that matured into United States Patent No. 5,578,313 (the “‘313 Patent”), entitled “Therapeutic Uses of Vitaletheine Modulators in Neoplasia”, was filed on October 4, 1994, as a divisional application of Application Serial No. 07/928,725, filed on August 12, 1992. The ‘313 Patent issued on November 26, 1996, with Knight and Scallen listed as inventors. Both Knight and Scallen signed a declaration of inventorship that they were the joint inventors of the subject matter claimed in Application Serial No. 07/928,725.
8. The patent application (Serial No. 08/463,732) that matured into United States Patent No. 6,096,536 (the “‘536 Patent”), entitled “In Vitro Cell Culture in Media Containing Beta-Alanyl-Taurine or Carbobenzoxy Beta-Alanyl-Taurine”, was filed on June 5, 1995, as a continuation application of a divisional application of United States Application Serial No. 07/941,926. The ‘536 Patent issued on August 1, 2000, with Knight and Scallen listed as inventors. Both Knight and Scallen signed a declaration of inventorship that they were the joint inventors of the subject matter claimed in Application Serial No. 07/941,926.

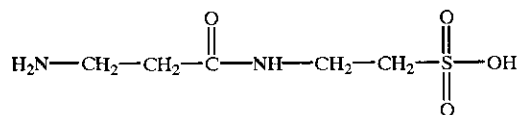
9. United States Patent Application Serial No. 08/463,784 (the “784 Application”), now entitled “In Vitro Cell Culture in Media Containing Beta-Alanyl-Taurine or Carbobenzoxy Beta-Alanyl-Taurine”, was filed on June 5, 1995, as a continuation application of a divisional application of Application Serial No. 07/941,926, with Knight and Scallen listed as inventors and is pending before the United States Patent and Trademark Office (“USPTO”). Both Knight and Scallen signed a declaration of inventorship as to Application Serial No. 07/941,926.
10. United States Patent Application Serial No. 08/466,143 (the “143 Application”), entitled “Use of Vitaletheine Modulators in the Prophylaxis and Treatment of Diseases”, was filed on June 6, 1995, as a continuation of Application Serial No. 07/910,892, with Knight and Scallen listed as inventors, and is pending before the USPTO. Both Knight and Scallen signed a declaration of inventorship as to United States Application No. 07/910,892.
11. United States Patent Application Serial No. 08/469,697 (the “697 Application”), entitled “Use of Vitaletheine Modulators in the Prophylaxis and Treatment of Diseases”, was filed on June 6, 1995, as a continuation of Application Serial No. 07/910,892, with Knight and Scallen listed as inventors, and is pending before the USPTO. Both Knight and Scallen signed a declaration of inventorship as to United States Application No. 07/910,892.
12. The ‘313 Patent, the ‘536 Patent, the ‘784 Application, the ‘143 Application, and the ‘697 Application are collectively referred to herein as the “Patents and Applications”.

D. Amendment of the Vitaethine Patent Applications

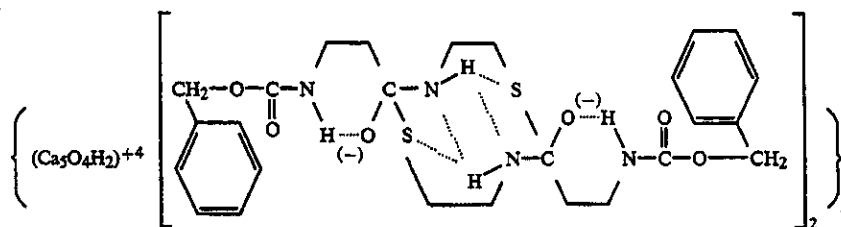
13. In the '313 Patent, the '536 Patent, the '784 Application, the '143 Application, and the '697 Application, the University, as the actual and equitable owner of the inventions that are the subject matter of these patents and applications, made certain amendments to the molecular structure of certain organic compounds disclosed and claimed in the specifications thereof. These amendments were made subsequent to filing of the application for each of the foregoing patents and applications during the ordinary course of prosecution of the applications. (The amendments made to the molecular structure of the organic compounds in each application, are, with respect to the change to the chemical structure, each referred to as the "Amendment".)
14. The Amendment to the Patents and Applications relates to an organic compound incorrectly named in the Patents and Applications as filed as "vitaethine V₄." The molecular structure contained in the Patents and Applications as filed was:



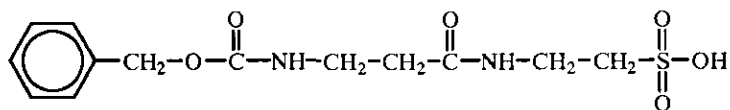
In the Amendment in each Patent and Application, the foregoing molecular structure was corrected with the following molecular structure (the “beta-alanyl-taurine Amendment”):



15. The Amendment to the Patents and Applications also relates to an organic compound incorrectly named in the Patents and Applications as the “benzyl derivative of vitaletheine.” The molecular structure contained in the Patents and Applications as filed was:



In the Amendment in each Patent and Application, the foregoing molecular structure was corrected to the following molecular structure (the “carbobenzoxy beta-alanyl-taurine Amendment”):



16. In the ‘313 Patent, the beta-alanyl-taurine Amendment and the carbobenzoxy beta-alanyl-taurine Amendment were accepted by the USPTO in both the specification and the claims following an initial rejection based on new matter.

17. In the '536 Patent, the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment were accepted by the USPTO in both the specification and the claims following an initial rejection based on new matter.
18. In the '784 Application, which has not yet issued as a patent, the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment were accepted by the USPTO in the claims following an initial rejection based on new matter.
19. In the '143 Application, which has not yet issued as a patent, the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment were accepted by the USPTO in the claims following an initial rejection based on new matter.
20. In the '697 Application, which has not yet issued as a patent, the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment were accepted by the USPTO in both the specification and the claims following an initial rejection based on new matter.
21. The defendants Knight and Scallen disagree with the Amendments, and maintain that the structures as set forth in the Patents and Applications prior to the Amendments are the correct molecular structures for the organic compounds.
22. In each of the '536 Patent, the '784 Application, the '143 Application, and the '697 Application, protests and other documents were filed by defendant Galen Knight with the USPTO; the protests and other documents appear in the prosecution history file of each of these Patents and Applications. These protests

included the same new matter arguments now raised by defendants Knight and Scallen with respect to the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment. Since the protests are a part of the official prosecution history file, they were presumptively considered by the Examiners in the USPTO.

23. A total of three different Examiners of the USPTO, each skilled in the relevant technology, have considered and accepted the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment as properly filed and as containing subject matter that was not new or in contravention of the Patent Laws, including specifically the “new matter” prohibition of 35 U.S.C. § 132, last sentence.
24. No amendment was made to the specification of the application maturing into U.S. Patent No. 5,370,868 that altered the molecular structure of any compound disclosed in the application as filed.

E. Synthesis of the Compounds that Led to the Correct Molecular Structures

25. Hauser Chemical Research, Inc. (“Hauser”), under the direction of Christopher Murray, Ph.D., (“Murray”), was retained by Dovetail Technologies, Inc. (“Dovetail”), the licensee of the University, to synthesize certain organic compounds, including vitalethine, vitaletheine V₄, and the benzyl derivative of vitaletheine, for use in preclinical studies and clinical trials by Dovetail.
26. Murray is expert in both synthetic organic chemistry and in process chemistry development of organic compounds, which includes expertise in developing the

most efficient and cost-effective method of manufacturing organic molecules in compliance with Good Manufacturing Practice standards mandated by the Food and Drug Administration for pharmaceutical products and active pharmaceutical ingredient materials.

27. Hauser was licensed by the Food and Drug Administration to make synthetic organic compounds for use as active pharmaceutical ingredient materials, and had made numerous different active pharmaceutical ingredient materials in compliance with Good Manufacturing Practice standards mandated by the Food and Drug Administration.
28. In developing an organic compound for potential use as an active pharmaceutical ingredient material, Murray initially follows the method of synthesis described by the developer of the organic compound. After having produced and characterized such organic compound, and utilizing his expertise and the results of literature searches on related compounds, Murray then employs techniques of process chemistry to optimize the processes and methods of synthesis of such organic compounds.
29. Murray and Hauser utilize state-of-the-art analytical techniques, including one- and two-dimensional carbon-13 nuclear magnetic resonance (^{13}C -NMR) and proton nuclear magnetic resonance (^1H -NMR), electrospray mass spectroscopy, elemental analysis and infrared spectroscopy, to analyze and characterize organic compounds.

30. The most definitive analytical technique for analysis, characterization and identification of organic compounds is one- and two-dimensional ^{13}C -NMR and ^1H -NMR.
31. Following the synthetic procedures for vitaletheine V_4 and the benzyl derivative of vitaletheine set forth in the Patents and Applications, Murray and Hauser synthesized organic compounds. The initial synthetic procedures followed by Murray and Hauser for vitaletheine V_4 and the benzyl derivative of vitaletheine were exactly in accordance with and followed the methods described in the Patents and Applications.
32. Murray and Hauser synthesized the organic compound called the benzyl derivative of vitaletheine following the exact synthetic method set forth in the Patents and Applications on thirteen separate occasions.
33. Murray and Hauser synthesized the organic compound called vitaletheine V_4 following the exact synthetic method set forth in the Patents and Applications on five to six separate occasions.
34. The organic compounds initially synthesized by Murray and Hauser following the synthetic methods for vitaletheine V_4 and the benzyl derivative of vitaletheine described in the Patents and Applications had the characteristics of the organic compounds of those names described in the Patents and Applications made in accordance with the methods and steps described in the Patents and Applications, and were the same organic compounds as disclosed in the Patents and Applications, as identified by methods of manufacture, ^{13}C -NMR data in the

Patents and Applications, ¹H-NMR data in the Patents and Applications, and other data and descriptions in the Patents and Applications.

35. Following the initial synthesis of vitaletheine V₄ and the benzyl derivative of vitaletheine utilizing exactly the methods and steps described in the Patents and Applications, Murray and Hauser then modified the synthetic methods, following accepted and conventional techniques of process chemistry, to optimize yield and manufacturing processes. The vitaletheine V₄ and the benzyl derivative of vitaletheine organic compounds made by Murray and Hauser following modified synthetic methods were the same organic compounds as those initially made by Murray and Hauser following exactly the methods described in the Patents and Applications, as verified by a variety of analytic test methods, including one- and two-dimensional ¹³C-NMR and ¹H-NMR, electrospray mass spectroscopy, elemental analysis and infrared spectroscopy.
36. Based on the structures assigned by Murray and Hauser for the organic compounds resulting from the synthesis of the organic compounds described as vitaletheine V₄ and the benzyl derivative of vitaletheine in the Patents and Applications, Murray and Hauser conducted literature searches, and identified an alternative route of synthesis for the compounds based upon a method referred to as the “modified Hungarian” or “Feuer” method (hereafter “Feuer method”). Identification of an alternative route of synthesis, and demonstration that the same organic compound results, is a recognized method of verifying the molecular structure and identity of an organic compound. Murray and Hauser determined

that the Feuer method produced the identical organic compounds as those made using the methods described for synthesis of vitaletheine V₄ and the benzyl derivative of vitaletheine in the Patents and Applications. This method proves that the molecular structures and identities assigned by Murray and Hauser for the compounds described as vitaletheine V₄ and the benzyl derivative of vitaletheine in the Patents and Applications are correct.

37. The organic compounds synthesized by Murray and Hauser that resulted from the methods described in the Patents and Applications for synthesis of vitaletheine V₄ and the benzyl derivative of vitaletheine did not have the molecular structures for vitaletheine V₄ and the benzyl derivative of vitaletheine depicted in the Patents and Applications as filed.
38. The organic compounds synthesized by Murray and Hauser that resulted from the methods described in the Patents and Applications for synthesis of vitaletheine V₄ and the benzyl derivative of vitaletheine were inherent in and the product of the methods described and set forth in the Patents and Applications.
39. Murray and Hauser correctly determined that the organic compounds described as vitaletheine V₄ and the benzyl derivative of vitaletheine did not have the molecular structures assigned to these organic compounds by Knight and Scallen in the Patents and Applications as filed.

F. Determination of the Correct Molecular Structures

40. Murray assembled an ad hoc group of national and internationally known experts, including professors at the University of Colorado, experts at Hauser, and

members of Dovetail's scientific advisory board, to analyze data relating to vitalethine V₄ and the benzyl derivative of vitalethine, and to determine the true and correct identity and molecular structure of the organic compounds called vitalethine V₄ and the benzyl derivative of vitalethine in the Patents and Applications.

41. Murray correctly determined that vitalethine V₄ was and is beta-alanyl-aurine and that the benzyl derivative of vitalethine was and is carbobenzoxy-beta-alanyl-aurine.

G. Inability to Synthesize Vitalizeine

42. Murray and Hauser made beta-alethine, the primary starting material for "vitalizeine" as described in the Patents and Applications, on numerous separate occasions. This included material made for use in human clinical trials under Food and Drug Administration mandated Good Manufacturing Practices. Murray and Hauser performed a formal structure proof of the beta-alethine they made, proving that that compound had the same structure as the known structure of beta-alethine. This included development of a reference standard of beta-alethine, with analytical tests including two-dimensional NMR, elemental analysis, purity tests and other tests and methods demonstrating that beta-alethine was made.
43. Murray and Hauser attempted, on at least twenty-six separate occasions, to synthesize the organic compound called "vitalizeine" in the Patents and Applications, following exactly the methods described in the Patents and Applications, and following modifications thereof based on the described method

of synthesis and known organic chemistry methodologies. Murray and Hauser further communicated with Knight concerning the synthetic method, and incorporated suggestions and information received from Knight with respect to the synthesis of “vitaethine.” Murray and Hauser further followed modifications in the method of synthesis as described by Knight and Scallen in a publication subsequent to the Patents and Applications. No organic compound resulted from these attempts meeting the description of “vitaethine” contained in the Patents and Applications.

44. Following both the methods described in the Patents and Applications for synthesis of “vitaethine” and alternative methods, including that method described by Knight and Scallen in a publication subsequent to the Patents and Applications, the primary resulting product obtained by Murray and Hauser was beta-alethine, which was the primary starting material described in the Patents and Applications used in the synthesis of “vitaethine.”

45. The testimony presented by Murray was credible and accurate.

H. Confirmation of Hauser and Murray Synthesis and Molecular Structures

46. After Hauser, through Dovetail, reported its results to the University, the University retained an expert consulting firm, Professional Analysis, Inc. (“PAI”), under the supervision of J. Shield Wallace, Ph.D., (“Wallace”) to synthesize and characterize certain of the organic compounds in accordance with the methods described in the Patents and Applications. PAI was specifically tasked to synthesize vitaetheine V₄, the benzyl derivative of vitaetheine, and vitaethine,

using its best efforts, by following the synthetic procedures set forth in the Patents and Applications.

47. Knight met with Wallace during the course of his efforts to synthesize the organic compounds, and Knight provided his interpretation of the synthetic methods, made suggestions as to the methods of synthesis, and provided a form of one reagent, zinc oxide, used in his earlier synthesis of certain of the organic compounds.
48. Following the synthetic procedures for vitaletheine V₄ and the benzyl derivative of vitaletheine set forth in the Patents and Applications, Wallace synthesized products. The synthetic procedures followed by Wallace and PAI for vitaletheine V₄ and the benzyl derivative of vitaletheine were exactly in accordance with and followed the methods described in the Patents and Applications.
49. The organic compounds synthesized by Wallace and PAI following the synthetic methods for vitaletheine V₄ and the benzyl derivative of vitaletheine described in the Patents and Applications had the characteristics of the organic compounds of those names described in the Patents and Applications, were made in accordance with the methods described in the Patents and Applications, and were the same organic compounds as disclosed in the Patents and Applications, as identified by methods of manufacture, ¹³C-NMR data in the Patents and Applications, ¹H-NMR data in the Patents and Applications, and other data and descriptions in the Patents and Applications.

50. The organic compounds synthesized by PAI that resulted from the methods described in the Patents and Applications for synthesis of vitaletheine V₄ and the benzyl derivative of vitaletheine did not have the molecular structures of vitaletheine V₄ and the benzyl derivative of vitaletheine depicted in the Patents and Applications.
51. The organic compounds synthesized by PAI that resulted from the methods described in the Patents and Applications for synthesis of vitaletheine V₄ and the benzyl derivative of vitaletheine were inherent in and the product of the methods described and set forth in the Patents and Applications.
52. Wallace correctly determined that the organic compounds described as vitaletheine V₄ and the benzyl derivative of vitaletheine did not have the molecular structures assigned to these organic compounds by the inventors in the Patents and Applications as filed.
53. Wallace correctly determined that vitaletheine V₄ was and is beta-alanyl-aurine and that the benzyl derivative of vitaletheine was and is carbobenzoxy-beta-alanyl-aurine.
54. Wallace and PAI attempted, on three separate occasions, to synthesize the organic compound called "vitalithine" in the Patents and Applications, following exactly the methods described in the Patents and Applications. No organic compound resulted from these attempts meeting the description of "vitalithine" contained in the Patents and Applications.

55. Following the methods described in the Patents and Applications for synthesis of “vitaethine,” the primary resulting product obtained by Wallace and PAI was beta-alethine, which was the primary starting material described in the Patents and Applications used in the synthesis of “vitaethine.”

56. The testimony presented by Wallace was credible and accurate.

I. The Evidence Does Not Support the Knight and Scallen Hypothesis that Vitaethine Exists

57. The criticisms and alleged defects in the syntheses performed by Hauser and PAI advanced in the protests filed by Knight and Scallen during pendency of the Patents and Applications, and reiterated during the course of this lawsuit, including the trial, were either scientifically incorrect or failed to identify any deviation from the method described in the Patents and Applications that would result in a different organic compound, and thus did not invalidate the syntheses of Hauser and PAI as proof that the chemical structures assigned in the applications as filed was incorrect.

58. The organic compound called “vitaethine” in the Patents and Applications is not a part of any Amendment at issue.

59. Knight admitted that he was the only person in the world known to him that claimed to have had successfully synthesized the product called and described as “vitaethine” in the Patents and Applications.

60. Knight admitted that he claimed to have synthesized the product called and described as “vitaethine” in the Patents and Applications on only three occasions.

61. Knight did not produce, and did not make, scientifically valid tests to fully characterize and identify the product he claimed to be “vitaethine” as described in the Patents and Applications. The data presented by Knight on “vitaethine” was equivocal or incomplete, and failed to include critical data as to testing conditions, tests conducted, comparative results between “vitaethine” and beta-alethine and other similar data.
62. The defendants Knight and Scallen did not preserve any of the alleged “vitaethine” compound, and did not provide any of the alleged “vitaethine” compound to either PAI or Hauser, despite its then availability and requests by PAI and Hauser, thereby casting doubt on the claims of defendants Knight and Scallen that an organic compound exists with a molecular structure as assigned in the Patents and Applications for vitaethine.

J. The Structures of the Amendments are Inherent in the Patents and Applications

63. The molecular structure disclosed in the beta-alanyl-aurine Amendment is implicit in and an inherent characteristic of the written disclosure and specification, as filed, of each of the Patents and Applications.
64. The molecular structure disclosed in the carbobenzoxy beta-alanyl-aurine Amendment is implicit in and an inherent characteristic of the written disclosure and specification, as filed, of each of the Patents and Applications.

65. The molecular structure disclosed in the beta-alanyl-aurine Amendment represents the true and correct organic compound resulting from the synthetic process for "vitalithine V₄" disclosed in the Patents and Applications as filed.
66. The molecular structure disclosed in the carbobenzoxy beta-alanyl-aurine Amendment represents the true and correct organic compound resulting from the synthetic process for the "benzyl derivative of vitalithine" disclosed in the Patents and Applications as filed.
67. The structures hypothesized by Knight and Scallen for vitalithine V₄, the benzyl derivative of vitalithine and "vitalithine", based on the expert opinions of Wallace and Murray, are inherently incredible and scientifically unsupported.

K. The Preponderance of the Evidence Establishes that the Amended Molecular Structures in the Patents and Applications are Correct

68. The University has proved by a preponderance of the evidence that following the method for vitalithine V₄ and the benzyl derivative of vitalithine, the correct chemical name of the organic compounds produced were beta-alanyl-aurine and carbobenzoxy beta-alanyl-aurine, respectively, and the correct molecular structures are as shown in the Amendments.
69. The University has proved by a preponderance of the evidence that the method for synthesizing vitalithine as described in the Patents and Applications, when followed, will yield primarily the same product with which the process began, namely, beta-alithine. Beta-alithine was well-known in the art long prior to the making of the inventions resulting in the Patents and Applications.

70. By a preponderance of the evidence, the facts at trial establish that the Examiners and the USPTO were correct in accepting the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment and that such amendments assign a molecular structure that is inherent in the organic compounds synthesized using the method described in the Patents and Applications.

L. Defendants Have Failed to Overcome the Presumption of Correctness by Clear and Convincing Evidence

71. The defendants Knight and Scallen have not overcome the presumption of correctness as to the Patents and Applications wherein the Amendments have been allowed.

72. The defendants Knight and Scallen have failed to prove, by clear and convincing evidence, that the Amendments to the Patents and Applications are not correct.

73. The defendants Knight and Scallen have failed to prove, by clear and convincing evidence, that the Amendments to the Patents and Applications assign molecular structures that are not inherent in the organic compounds synthesized using the method described in the Patents and Applications, and as characterized by data in the Patents and Applications.

74. As determined by the Court in entering summary judgment as to Count IV, Knight and Scallen breached their contractual obligations to the University by failing to execute assignments to the Vitaletine Patents and Applications. The University is the true and lawful owner of U.S. Patent No. 5,370,868, as to which no amendment to the molecular structure of any compound therein was made.

The University is the true and lawful owner of all other Patents and Applications included within the Vitaletheine Patents and Applications.

Conclusions of Law

1. The Court has personal jurisdiction over the parties.
2. Venue is properly laid in the District of New Mexico pursuant to 28 U.S.C. § 1400(b).
3. The rights of Plaintiff University to relief necessarily depend on resolution of one or more substantive questions of United States Patent Law.
4. The relief sought by Plaintiff University in Count III pursuant to 35 U.S.C. § 256 necessarily arises under the United States Patent Law for which federal courts have exclusive jurisdiction.
5. This Court has subject matter jurisdiction over the claims now pending.
6. The last sentence of 35 U.S.C. § 132 provides as follows: “No amendment shall introduce new matter into the disclosure of the invention.”
7. Determination of whether an amendment introduces new matter “depends on the facts of the case: the nature of the disclosure, the state of the art, and the nature of the added matter.” Brooktree Corporation v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1574 (Fed. Cir. 1993).
8. If new matter in contravention of 35 U.S.C. § 132 is introduced during prosecution of a patent application, then claims depending on or incorporating such new matter are invalid under 35 U.S.C. § 112, ¶ 1. Waldmar Link, GmbH & Co. v. Osteonics Corp., 32 F.2d 556, 558 (Fed. Cir. 1994); Transco Prod., Inc. v.

Performance Contracting, Inc., 38 F.3d 551, 558 (Fed. Cir. 1994); SDS USA, Inc. v. Ken Specialties, Inc., 122 F.Supp.2d 533, 544 (D.N.J. 2000).

9. A patent is presumed valid. 35 U.S.C. § 282.
10. A determination by the Patent and Trademark Office that an amendment does not introduce “new matter” as defined in 35 U.S.C. § 132 is entitled to an especially weighty presumption of correctness:

Whether particular technological information is "new matter" depends on the facts of the case: the nature of the disclosure, the state of the art, and the nature of the added matter. A patent is presumed valid, and this presumption is based in part on the expertise of the patent examiners presumed to have done their job. This presumption, which may be viewed as a presumption of administrative correctness, as applied to a new matter determination was discussed by our predecessor court, which stated that "the fact that the Patent Office allows . . . an amendment without objection thereto as new matter (within the meaning of 35 U.S.C. § 132) is entitled to an especially weighty presumption of correctness."

Brooktree Corporation v. Advanced Micro Devices, Inc., 977 F.2d at 1574-75; accord, In re Smythe, 480 F.2d 1376, 1385 n. 5, (CCPA 1973); Technicon Instruments Corp. v. Coleman Instruments, Inc., 255 F.Supp. 630 (N.D.Ill. 1966), aff'd, 385 F.2d 391 (7th Cir. 1967).

11. The rule applied is “that a structural formula may be corrected without violation of 35 USC § 132, if ‘there is sufficient evidence in the record to show the (proposed structure) to be an inherent characteristic of the subject matter so

identified””, Ex parte Marsili, 214 U.S.P.Q. 904, 906 (Bd.Pat.App., 1979),
quoting from In re Magerlein, 346 F.2d 609, 611 (C.C.P.A. 1965).


12. The organic compounds described in the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment inherently had, when the Patents and Applications were filed, and now have, the molecular structures given in the Amendments. “[T]he products described, exemplified and claimed . . . inherently had and have now the structure given in the amendment in question.” Ex parte Marsili, 214 U.S.P.Q. at 906.
13. The Amendments do not, as a matter of law, introduce “new matter” into the Patents and Applications in contravention of 35 U.S.C. § 132.
14. Defendants Knight and Scallen have failed to prove, by clear and convincing evidence, that the ‘313 Patent and the ‘536 Patent are invalid.
15. Defendants Knight and Scallen have failed to prove, by clear and convincing evidence, that the Amendments introduced “new matter” into the Patents and Applications in contravention of 35 U.S.C. § 132.
16. The Defendants Knight and Scallen are the properly named and sole inventors of the Patents and Applications as amended.
17. The Plaintiff University is the true and lawful owner of all right, title and interest to the Patents and Applications, including the ‘313 Patent, the ‘536 Patent, the ‘784 Application, the ‘143 Application, and the ‘697 Application, together with any patent or application, foreign or domestic, that is a continuation or divisional

application of any of the foregoing, or which is a continuation or divisional application of a predecessor of any of the foregoing.

18. Defendants Knight and Scallen are the only, joint and properly named inventors of the '313 Patent and the '536 Patent.
19. Defendants Knight and Scallen are the only, joint and properly named inventors of the inventions disclosed in the '784 Application, the '143 Application, and the '697 Application, including without limitation the Amendments.
20. The Plaintiff University is the true and lawful owner of all right, title and interest to U.S. Patent No. 5,370,868, as to which no amendment to the structure of any compound therein was made, and all other patent applications included within the Vitaletheine Patents and Applications as to which no amendment was made as to the structure of any compound included therein.

Dated this 24th day of July, 2001.

PEACOCK MYERS & ADAMS, P.C.

By: 
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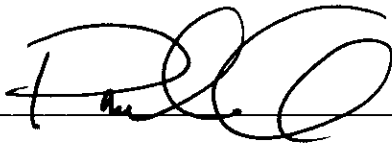
ATTORNEYS FOR PLAINTIFF THE REGENTS
OF THE UNIVERSITY OF NEW MEXICO

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing pleading was sent via first class mail this 24th day of July, 2001 to the following:

Galen D. Knight
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